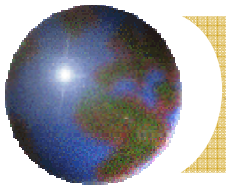


Hortencia Hornbeak, Ph.D.
Associate Director for Review and Policy

Scientific Review Program, DEA, NIAID

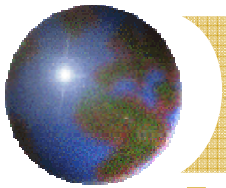


Leadership for HIV/AIDS Clinical Trials Networks

Agenda/Overview

- ◆ **RFA**
- ◆ **Eligibility for Applying**
- ◆ **Submission Options**
- ◆ **Tentative Review Plan**
- ◆ **Submission Recommendations**
- ◆ **Standard Review**
- ◆ **Additional Review Criteria for RFA**
- ◆ **Other Policy Requirements**

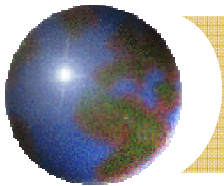




Leadership for HIV/AIDS Clinical Trials Networks

Mechanisms of Support

- ◆ **U01 award mechanism(s)**
- ◆ **Applicants solely responsible for planning, directing, and executing the proposed project**
- ◆ **Just-in-time concepts**
- ◆ **Non-modular budget formats**

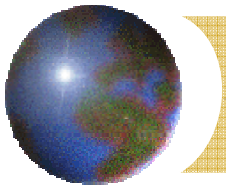


Leadership for HIV/AIDS Clinical Trials Networks

Eligible Institutions

- ◆ **For-profit & non-profit organizations**
- ◆ **Public or private institutions, such as universities, colleges, hospitals, and laboratories**
- ◆ **Units of state & local government**
- ◆ **Eligible agencies of the Federal government**
- ◆ **Domestic institutions/organizations**





Leadership for HIV/AIDS Clinical Trials Networks

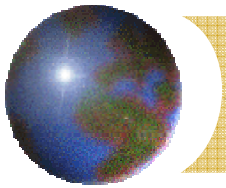
Foreign Institutions

Foreign institutions are not eligible to apply as the awardee institution for any component.

Foreign institutions are eligible to participate as collaborators in Network activities including:

- ◆ **Operations**
- ◆ **Statistical and Data Management**
- ◆ **Network Laboratory Structure**





Leadership for HIV/AIDS Clinical Trials Networks

Receipt, Review, Important Dates:

Letters of Intent Receipt: *April 11, 2005*

Application Receipt: *May 11, 2005*

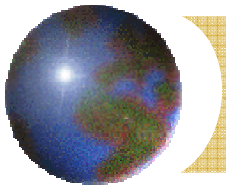
Applications due at NIH on the receipt date

Peer Review: *October, 2005*

Council Review: *January, 2006*

Anticipated Start: *March, 2006*



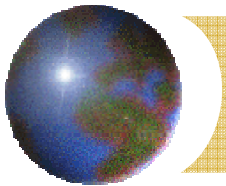


Leadership for HIV/AIDS Clinical Trials Networks

Letter of Intent

- ◆ **Number and title of this funding opportunity**
- ◆ **Title of proposed research**
- ◆ **Name, address, and telephone number of
the Principal Investigator**
- ◆ **Names of other key personnel**
- ◆ **Participating institutions**





Leadership for HIV/AIDS Clinical Trials Networks

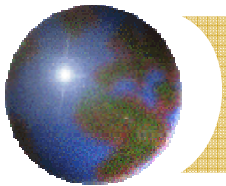
Letter of Intent (continued)

Optional:

Encourage you to include:

- ◆ **Planned scientific area(s) covered**
- ◆ **The components (CORE, Lab, SDMC) included in the application**





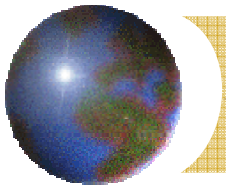
Leadership for HIV/AIDS Clinical Trials Networks

Submission Options

Each Leadership Network Will Consist of the Following Three Components:

- ◆ **The Coordinating and Operations Center
(CORE)**
- ◆ **The Network Laboratory Structure**
- ◆ **The Statistical and Data Management Center
(SDMC)**





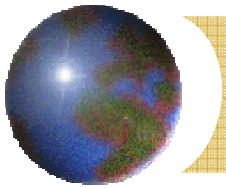
Submission Options (continued)

The Three Components may be Submitted as:

❖ **One Application** = **(CORE + Lab + SDMC)**

❖ **Two Applications** = **(CORE + Lab) + SDMC**
or **(CORE + SDMC) + Lab**
or **(SDMC + Lab) + CORE**

❖ **Three Separate Applications** = **CORE , Lab , SDMC**



Leadership for HIV/AIDS Clinical Trials Networks

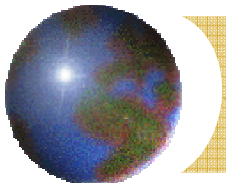
Submission Options (continued)

Assembly of Applications

Each application must contain a section called:

**“Overview of the Entire Network
Leadership Application”**





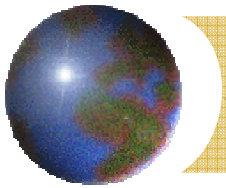
Leadership for HIV/AIDS Clinical Trials Networks

Submission Options (continued)

The Table of Contents for the Network application can be found on the web at: http://www.niaid.nih.gov/daids/rfa/network06/required_forms.htm

<u>Overview of Entire Network Leadership Application (Required)</u>
1. Summary Sheet (do not use PHS 398 Face Page)
2. PHS 398 Form Page 2
3. Leadership Table 2
4. Detailed Budget for Initial Budget Period
5. Budget for Entire Proposed Period of Support
6. Network Overview (20 pages or less):
i. Mission
ii. Organization
iii. Key Personnel
iv. Coordination
v. Special Features



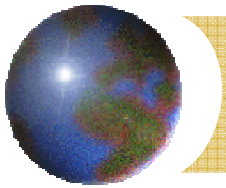


Submission Options (continued)

Assembly of Applications

The overview provides context for the reviewers.

This section should be identical in all applications if the three components are submitted in more than one application.

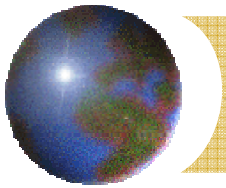


Submission Options (continued)

Participation in Multiple Networks

Institutions/investigators may collaborate with more than one Network.

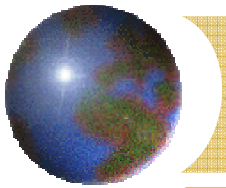
Benefits from sharing central resources should be stated.



Tentative Review Plan

Separate Special Emphasis Panels (SEP) will review the:

- ◆ **Statistical and Data Management Center (SDMC) components**
- ◆ **Network Laboratory Structure components**

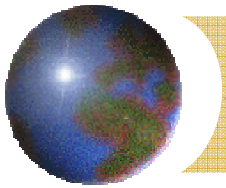


Tentative Review Plan (continued)

Six Research Areas:

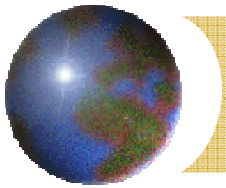
- ◆ **Vaccine Research and Development**
- ◆ **Translational Research/Drug Development**
- ◆ **Optimization of Clinical Management,
including Co-Morbidities**
- ◆ **Microbicides**
- ◆ **Prevention of Mother-to-Child
Transmission of HIV**
- ◆ **Prevention of HIV Infection**





Tentative Review Plan (continued)

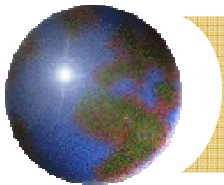
**Multiple Special Emphasis
Panels (SEPs) will review the six
Research Areas respectively
within the CORE components.**



Tentative Review Plan (continued)

Summaries of these SEP reviews will go to a Master SEP that will include:

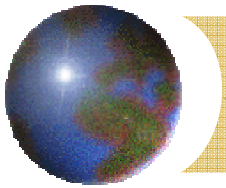
- ◆ Members of the previous SEPs**
- ◆ Additional expertise in management and coordination of large, multi-institutional programs**



Tentative Review Plan (continued)

**This Master SEP will award
overall scores for:**

- ◆ **CORE components**
- ◆ **Combined applications**



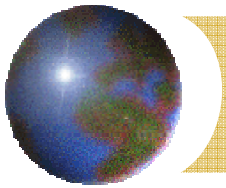
Leadership for HIV/AIDS Clinical Trials Networks

Tentative Review Plan (continued)

Scores will be given to:

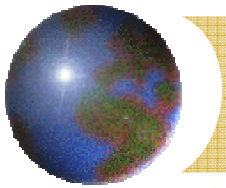
- ◆ **Each scientific area proposed**
- ◆ **Each component (CORE, Lab, SDMC)**
- ◆ **Each application as a whole**





Tentative Review Plan (continued)

**Final decisions on Network Awards
will be made through a deliberative
process developed by the DAIDS.**



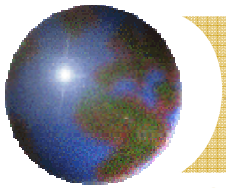
Leadership for HIV/AIDS Clinical Trials Networks

Submission Recommendations

To facilitate the review:

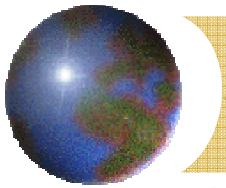
**Each component should refer back
to other relevant area(s) of the
application(s).**





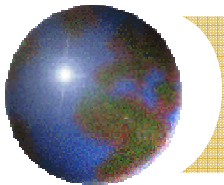
Submission Recommendations (continued)

Scientific areas should address the personnel, facilities and approaches that are described in more detail in the SDMC and Network Laboratory Components or applications.



Submission Recommendations (continued)

**Make it easy for reviewers to
see the integrated nature of
your Network Components.**



Leadership for HIV/AIDS Clinical Trials Networks

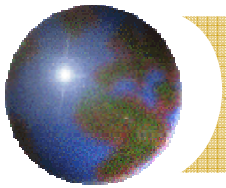
Peter R. Jackson, Ph.D.
***Chief, AIDS Clinical and Epidemiology
Research Review Branch***

Scientific Review Program, DEA, NIAID

Phone: (301) 496-8426 Fax: (301) 480-2310

Email: Pjackson@niaid.nih.gov



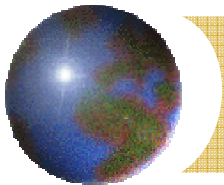


Leadership for HIV/AIDS Clinical Trials Networks

Merit Review Criteria

- 1. Significance**
- 2. Approach**
- 3. Innovation**
- 4. Investigators**
- 5. Environment**

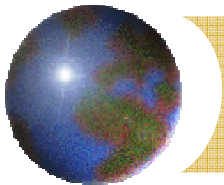




Merit Review Criteria

Significance

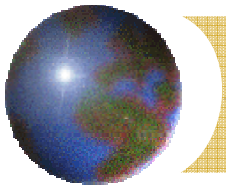
Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?



Merit Review Criteria

Approach

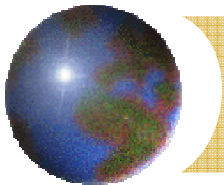
Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?
Does the applicant acknowledge potential problem areas and consider alternative tactics?



Merit Review Criteria

Innovation

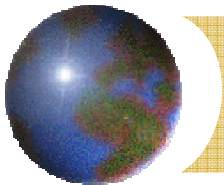
Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?



Merit Review Criteria

Investigators

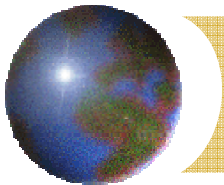
Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?



Merit Review Criteria

Environment

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?



Leadership for HIV/AIDS Clinical Trials Networks

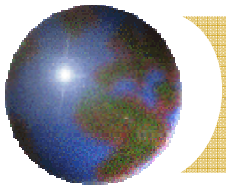
Review and Selection Process

Individual numerical merit scores initially will be assigned to each component:

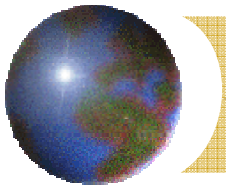
- ◆ **The Coordinating and Operations Center**
- ◆ **The Network Laboratory Structure**
- ◆ **The Statistical and Data Management Center**

An overall priority score will be assigned to each application based on review and merit of the individual components and the merit of the whole application.





Additional Review Criteria For RFA

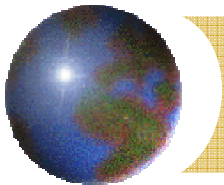


Leadership for HIV/AIDS Clinical Trials Networks

Application Review Information

**Overlaid upon the Merit Review Criteria,
the following items will be considered in the
determination of scientific merit and the
priority score.**



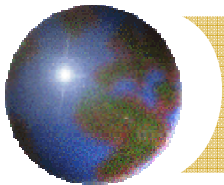


Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria

- ◆ **The Coordinating and Operations Center
(CORE)**
- ◆ **The Network Laboratory Structure**
- ◆ **The Statistical and Data Management Center
(SDMC)**



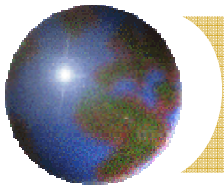


Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-CORE

- 1. Network Clinical Research Plan (3)**
- 2. Cross-Network Collaborations (3)**
- 3. Network Structure and Leadership (6)**
- 4. Network Policy and Procedures (8)**
- 5. Operations Center (8)**





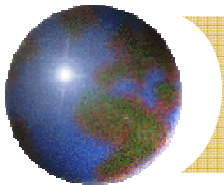
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-CORE

Network Clinical Research Plan

- ❖ **Scientific merit, innovation, and feasibility of the proposed research plan.**
- ❖ **Potential for research to advance HIV prevention or clinical care.**
- ❖ **Potential for research to be applicable to groups most severely impacted by HIV/AIDS.**





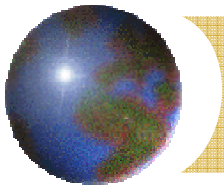
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-CORE

Cross-Network Collaborations

- ◆ **Plans for collaboration and integration with other groups.**
- ◆ **Potential to pursue scientific questions for Scientific Leadership to enable, cross-Network scientific collaborations.**
- ◆ **Potential to increase organizational efficiency and effectiveness with other DAIDS and NIH-sponsored HIV/AIDS Clinical Trial Networks.**





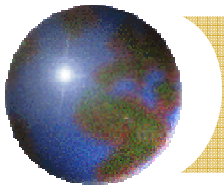
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-CORE

Network Structure and Leadership

- ◆ **Adequacy of the Principal Investigator's qualifications, time commitment, experience and vision.**
- ◆ **Adequacy of the Scientific Leadership's qualifications, time commitment, and experience.**
- ◆ **Appropriateness of the organizational structure and lines of authority for the Network.**
- ◆ **Appropriateness of the proposed size and structure of the Network to meet scientific goals.**



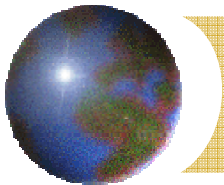


Additional Review Criteria-CORE

Network Structure and Leadership (continued)



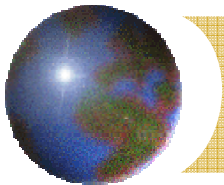
Appropriateness of criteria and standards to select and propose clinical sites to meet Network needs, including timely enrollment in clinical research, population demographics, clinical site leadership and past performance.



Additional Review Criteria-CORE

Network Structure and Leadership (continued)

❖ **Adequacy of plans for management and communication among the Operations Center, Network Laboratories, Statistical and Data Management Center, and Clinical Trial Units/sites.**



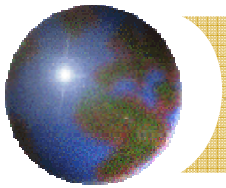
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-CORE

Network Policy and Procedures

- ◆ **Plans to protect rights and safety of subjects.**
- ◆ **Plans to guarantee data quality and integrity.**
- ◆ **Plans to maintain accurate and timely information on progress.**
- ◆ **Plans to include safeguards to terminate studies.**

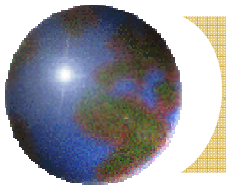




Additional Review Criteria-CORE

Network Policy and Procedures (continued)

- ❖ **Strength of policies and procedures to reassess, and evaluate scientific priorities.**
- ❖ **Appropriateness of the plan to assess the productivity of the Network and Network components and to correct inadequate performance.**



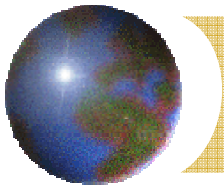
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-CORE

Network Policy and Procedures (continued)

- ❖ **Plans to manage and allocate the Protocol Implementation Fund.**
- ❖ **Plans to develop/nurture community relationships and involve community representatives.**

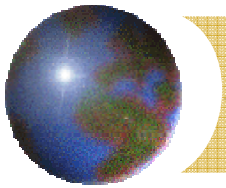




Additional Review Criteria-CORE

Network Policy and Procedures (continued)

- ❖ **Appropriateness of policy and plans to monitor and manage conflicts of interest.**
- ❖ **Appropriateness of plan to involve new investigators, foster the participation of women and racial/ethnic minority researchers, and ensure their participation in Network activities.**

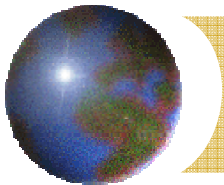


Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-CORE

Operations Center

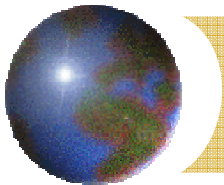
- ◆ **Adequacy of the qualifications of the Operations Center Director.**
- ◆ **Adequacy of the qualifications of the other key personnel.**
- ◆ **Appropriateness of the organizational structure, management plan and lines of authority.**



Additional Review Criteria-CORE

Operations Center (continued)

- ◆ Adequacy of plan to facilitate rapid and effective communications.
- ◆ Adequacy of plan to assure fiscal and operational accountability.
- ◆ Adequacy of plan to support and track protocol development, track protocol development and implementation, provide research administration, and manage regulatory documents.

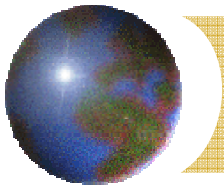


Additional Review Criteria-CORE

Operations Center (continued)

- ◆ **Plans and staffing to support network activities, including an Executive Committee, scientific and resource committees, field staff training, and Network meetings.**

- ◆ **Adequacy of resources to support the Network research plans and priorities.**

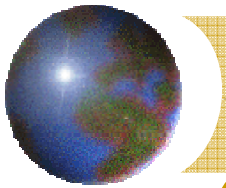


Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-Network Laboratory

Network Laboratory Components

- 1. Structure and Leadership (5)**
- 2. Policy and Procedures (5)**
- 3. Communication and Collaboration (2)**



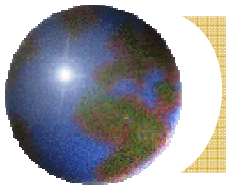
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-Network Laboratory

Structure and Leadership

- ◆ **Proposed number, type and location of laboratories.**
- ◆ **Organizational structure, management plan and lines of authority.**
- ◆ **Qualifications of the Network Laboratories Principal Investigator.**





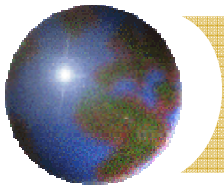
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-Network Laboratory

Structure and Leadership (continued)

- ◆ **Qualifications and experience of the Director and key personnel at each identified Laboratory.**
- ◆ **Plan to provide resources to support Network Laboratories.**





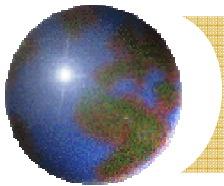
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-Network Laboratory

Policy and Procedures

- ◆ **Plans to select laboratory tests for clinical studies.**
- ◆ **Plans for laboratory services (facilities, staff, standard operating procedures, laboratory data management, and specimen tracking).**
- ◆ **Plans to evaluate new technologies and feasibility of technology transfer to Network laboratories.**



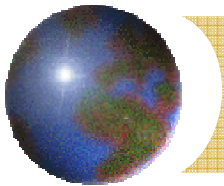


Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-Network Laboratory

Policy and Procedures (continued)

- ◆ **Plans to train Network laboratory staff.**
- ◆ **Plans for laboratory QA/QC, adherence to guidelines of regulatory agencies and participation in external quality assurance programs.**

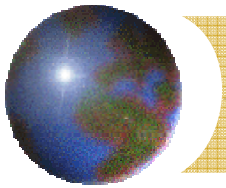


Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria-Network Laboratory

Communication and Collaboration

- ◆ **Plans for rapid and effective communication among laboratories and other Network structures.**
- ◆ **Plans to contribute to efforts to maximize organizational efficiency and effectiveness through collaborations.**
 - (Share laboratory resources and procedures)**
 - (Develop consistent assay and standards)**



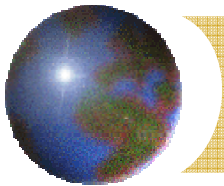
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Additional Review Criteria-SDMC

Statistical and Data Management Center (SDMC)

- 1. Structure and Leadership (4)**
- 2. Policy and Procedures (4)**
- 3. Communication and Collaboration (2)**





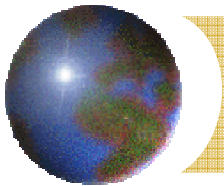
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Additional Review Criteria-SDMC

Structure and Leadership

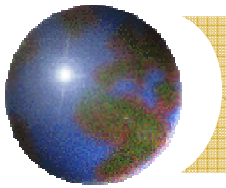
- ◆ **Principal Investigator's qualifications to direct a multi-center clinical trials statistical and data management center.**
- ◆ **Qualifications, training, and experience of other key personnel.**
- ◆ **Organizational structure, management plan, and of authority.**
- ◆ **Proposed resources to support the Network research plans and priorities.**





Policy and Procedures

- ◆ **Plans to conduct interim, final analyses of clinical studies.**
- ◆ **Potential scientific contribution to Network clinical research through participation in design, conduct, analysis and publication.**

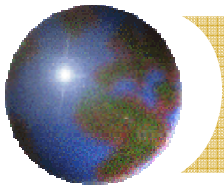


Policy and Procedures (continued)

◆ Plans and procedures to provide data management to the Network:

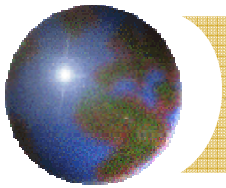
(Database design, security, confidentiality and administration, randomization/registration, data collection, quality control, data retrieval, report generation, site training).

◆ Plans for reliable electronic mail among Network components and DAIDS.



Communication and Collaboration

- ❖ **Plans for rapid and effective communication within SDMC and with Network structures.**
- ❖ **Plans to facilitate cross-Network collaboration and coordination.**



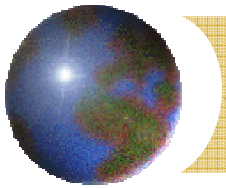
Leadership for HIV/AIDS Clinical Trials Networks

Additional Review Criteria

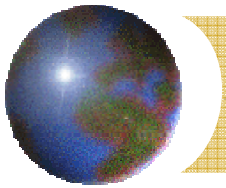
The following items will be considered in the determination of scientific merit and the priority score:

- ◆ **Protection of Human Subjects from Research Risk.**
- ◆ **Inclusion of Women, Minorities and Children in Research.**





Additional Policy Requirements

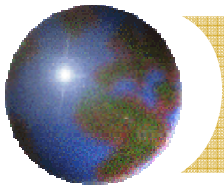


Leadership for HIV/AIDS Clinical Trials Networks

Data Sharing Plan

- ◆ The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers.
- ◆ The data sharing plan will be part of the terms and conditions of the award.
- ◆ The funding organization will be responsible for monitoring the data sharing policy.





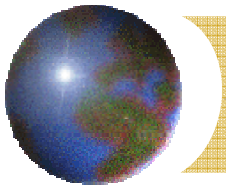
Leadership for HIV/AIDS Clinical Trials Networks

Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication.

Investigators should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.





Leadership for HIV/AIDS Clinical Trials Networks

Sharing Research Resources

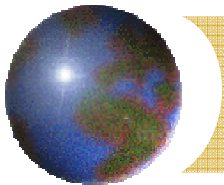
Review the NIH Grants Policy Statement:

[http://grants.nih.gov/grants/policy/nigps/
part_ii_5.htm#availofrr](http://grants.nih.gov/grants/policy/nigps/part_ii_5.htm#availofrr)

and

http://ott.od.nih.gov/newpages/rtguide_final.html



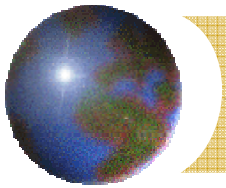


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Sharing Research Resources (continued)

- ◆ **The adequacy of the resources sharing plan will be considered by the funding organization when making funding recommendations.**
- ◆ **Program staff may negotiate modifications of the data and resource sharing plans before recommending funding.**
- ◆ **Final version of the negotiated data and resource sharing plans will become a condition of the grant award.**





Questions?